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Forum

The 100,000 Lives Campaign:
A Scientific and Policy Review

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The authors were invited by the Journal *to prepare a commentary on the Institute for Healthcare Improvement's 100,000 Lives Campaign, which had recently observed the end of its initial 18-month effort.*

On December 14, 2004, Dr. Don Berwick, the well-respected founder and chief executive officer (CEO) of the Institute for Healthcare Improvement (IHI), dramatically tossed down an unprecedented gauntlet at IHI's annual Orlando meeting. Impatient with the pace of change in patient safety and quality and with vague goals ("some is not a number, soon is not a time," he chanted), he announced a "campaign to save 100,000 lives" in the next 18 months in American hospitals.[1] The effort's structure and focus would be modeled on a political campaign, complete with precinct captains and campaign nodes.[2]

Dr. Berwick had a point. Five years after the Institute of Medicine (IOM) reports on medical errors and health care quality[3,4] action was largely driven by mandates (particularly Joint Commission on Accreditation of Healthcare Organization standards) and public reporting systems (whose modus operandi is largely to shame underperforming organizations into improvement). Conceptually, the idea of a campaign catalyzed by front-line workers "doing the right thing" was attractive. IHI, an organization with a large reservoir of established credibility, a highly respected and charismatic leader, and close connections to many hospitals and health care systems, was well positioned to lead such a campaign, despite (or perhaps because of) its absence of regulatory authority or formal role in the health care hierarchy.

Eighteen months later, on June 14, 2006, IHI proudly announced that the campaign had far surpassed its goal,

Article-at-a-Glance

Background: On June 14, 2006, the Institute for Healthcare Improvement (IHI) announced that its campaign to save 100,000 lives had far surpassed its goal—by saving 122,300 lives.

The Interventions: Although many of the campaign's six "evidence-based practices" are supported by relatively strong evidence, the use of rapid response teams (the only intervention not already required or promoted by a major federal or Joint Commission initiative) is not.

The "Lives Saved": Secular trends could account for many of the "lives saved," which IHI acknowledges (and could have adjusted for, resulting in a markedly lower "lives saved" estimate). Moreover, IHI's estimates of lives saved are dependent on the case-mix adjustment—accounting for nearly three out of four "lives saved." The actual mortality data were supplied without audit by the more than 3,000 participating hospitals, and 14% of the hospitals submitted no data at all.

Policy Implications: IHI established and promoted a set of achievable goals for American hospitals and generated unprecedented amounts of social pressure for hospitals to participate. This remarkable achievement should be studied by other organizations seeking to generate widespread change in the health care field.

Conclusions: Although the 100,000 Lives Campaign succeeded in catalyzing efforts to improve safety and quality in American hospitals, the promotion of rapid response teams as a national standard is problematic, and methodologic concerns regarding the "lives saved" calculations make it difficult to interpret the campaign's true accomplishments.

Table 1. The Six Practices ("Planks") in IHI's 100,000 Lives Campaign*

Practice	No. of Participating Hospitals†	Other Major Organizations Promoting/Mandating Practice‡	Strength of Evidence§
Rapid Response Teams	1,781	None	Relatively Weak
Medication Reconciliation	2,185	JCAHO	Weak–Medium
Prevent Central Line Infections	1,925	JCAHO	Strong
Prevent Surgical Site Infections	2,133	JCAHO, CMS	Strong
Prevent Ventilator-Associated Pneumonia	1,982	JCAHO, CMS	Strong
Evidence-Based Care for Myocardial Infarction	2,288	JCAHO, CMS, NQF	Strong

* IHI, Institute for Healthcare Improvement; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; CMS, Centers for Medicare & Medicaid Services; NQF, National Quality Forum.

† Institute for Healthcare Improvement: *IHI Announces that Hospitals Participating in 100,000 Lives Campaign Have Saved an Estimated 122,300 Lives* (press release). http://www.ihi.org/NR/rdonlyres/1C51BADE-0F7B-4932-A8C3-0FEFB654D747/0/UPDATED100kLivesCampaignJune14milestonepressrelease.pdf (last accessed Aug. 30, 2006).

‡ Institute for Healthcare Improvement: *100,000 Lives Campaign: Alignment with National Healthcare Improvement Initiatives.* Dec. 8, 2005. http://www.ihi.org/NR/rdonlyres/CC960DDD-2BB3-41C1-9D56-B957876C9C1B/0/AlignmentWithNationalHealthcareImprovementInitiatives.pdf (last accessed Aug. 30, 2006).

§ Authors' assessment, based in part on Shojania K.G, et al.: *Making Health Care Safer: A Critical Analysis of Patient Safety Practices.* Agency for Healthcare Research and Quality, AHRQ Publication no. 01-E058. http://www.ahcpr.gov/clinic/ptsafety/ (last accessed Aug. 30, 2006) and other literature.

by "saving 122,300 lives." Although IHI's background materials were replete with caveats,[5,6] its press release[7]—and the accompanying media coverage[8,9]—was not. The clear message was that the campaign and its six "evidence-based interventions" (Table 1, above) had led to this remarkable reduction in national mortality.

In this article, we examine the 100,000 Lives Campaign from a scientific and policy perspective. We begin by considering the scientific underpinnings behind the campaign's six "planks" and go on to analyze the validity of the campaign's claim to have saved 122,300 lives. We end with a discussion of the policy implications of and the lessons learned from the campaign.

The Interventions

As the campaign's focal point, IHI chose "evidence-based practices" in six clinical areas ("planks"), practices whose widespread implementation would, presumably, result in the saving of 100,000 lives in 18 months. The discussion on IHI's Web site regarding how these planks were selected, whether the practices were based on national priorities, and whether evidence as well as costs and benefits would favor their use is limited; perhaps unsurprisingly, the six interventions appear to be ones that the organization had focused on (including creating tools to support implementation) in the past.

In fact, many of the practices promoted by the IHI campaign are supported by relatively strong evidence, including strategies to avoid ventilator-associated pneumonia, central line infections, surgical site infections, and mortality after acute myocardial infarction (AMI; Table 1). The evidence supporting medication reconciliation to prevent prescribing errors is more limited, and its relative importance among the various strategies to prevent adverse drug events (for example, computerized order entry and decision support, pharmacists on the wards) is uncertain.[10] Interestingly, in precampaign estimates of the likely number of lives saved by virtue of implementation of the six interventions, the largest impact was projected to come from the implementation of rapid response teams, an intervention with reasonably high face validity but whose only randomized trial showed no benefit.[11]

Because the quality improvement and patient safety external environments are so active, many of these planks' practices were already being promoted (or mandated) by other organizations. For example, the acute MI and surgical site infection practices are part of both the Joint Commission's and the Centers for Medicare & Medicaid Services (CMS)'s hospital quality measure sets.[12] Medication reconciliation was posted on the Joint Commission's Web site for field review in April 2004—and was approved in May 2005 as a 2006 Joint

Commission National Patient Safety Goal.*[13] IHI acknowledges and applauds this "alignment" in its campaign materials.[14] The only one of the six processes that was not already being required or promoted by a major federal or Joint Commission initiative was rapid response teams, probably because the state of the evidence and the uncertainty regarding appropriate implementation would not have supported such a mandate (Table 1).

Given these conditions, it is extremely difficult to estimate the marginal impact of the campaign on the implementation of these six practices. It does seem likely that the overall speed and quality of implementation were accelerated by the campaign, both through the energy that the campaign generated and the guidance and materials that IHI made available to hospitals via its Web site and many physical and virtual meetings. However, it is presently impossible to determine the extent of any incremental benefit the campaign may have created above existing efforts.

The "Lives Saved"

After early indications that the campaign was running behind schedule in lives saved, IHI's June 14, 2006 announcement that the campaign had far exceeded its mortality goal was stunning. It gave the appearance that the campaign was an unprecedented success—the metaphorical election was won. Our comments about these mortality estimates will focus on two areas. First, are the numbers right? Second, can the "lives saved" be attributed to the campaign?

Are the Numbers Right?

IHI's estimates of lives saved are derived by comparing each participating hospital's actual deaths (from hospital self-reports) during each month of the campaign to "expected deaths"—generated from that hospital's mortality rate in the same month of a base year (2004). This strategy was designed to allow a month-to-month comparison (for example January 2005 and January 2006 were both compared to January 2004), thereby correcting for seasonal trends.[1,2,5,6] Because of the possibility of changes in clinical complexity, a case-mix adjustment methodology was "provided without restriction from two independent organizations," CareScience and Solucient[5]; a third adjustment strategy (that of the Premier organization) was apparently added later.[6] The actual methodology for these adjustments, on which the estimates are highly dependent (the raw death rate difference was only approximately 33,000–the case-mix adjustment led to the additional 89,000 "lives saved"[15]) is not described in the IHI materials, but the organization notes that all three methods yielded similar results.[6] Case-mix adjustment is an inexact science at best; when done well, it is fair to say that the playing field is leveled but remains somewhat bumpy,[16] particularly when the adjustments flow from administrative data.[17] For example, we know of several hospitals that have undertaken aggressive efforts to "improve" their administrative coding, seeking to capture additional reimbursement and enhance their observed-to-expected mortality ratios. Such efforts, if widespread, would have the effect of spuriously increasing the apparent severity of illness in hospitals in the United States, in turn resulting in inaccurate numbers of "lives saved" after applying IHI's adjustments. Taken as a whole, we are unable to evaluate from the information provided by IHI whether the case-mix adjustment—which accounted for nearly three out of four "lives saved"—would withstand rigorous scientific review.

The actual mortality data were supplied without audit by the more than 3,000 participating hospitals, a choice made, according to IHI, "because of the voluntary nature of the project, the amount of work associated with data collection and submission…needed to be kept to a minimum."[5(p. 1)] Moreover, not all hospitals submitted data—approximately 14% of "participating hospitals" submitted no data at all.[6,15] The results of nonsubmitting hospitals were imputed from those of the submitting institutions, an extrapolation that violates the general epidemiologic principle that nonresponders tend to be systematically different from responders. Moreover, the reports from even those hospitals that did submit data were usually incomplete. The most striking example of this is the fact that the IHI "milestone" announcement of "lives saved in 18 months" was based on submissions through March, not June, 2006[6]—these

* Goal 8, "Accurately and completely reconcile medications across the continuum of care."

final three months were also extrapolated from hospitals' previous submissions. Although not reported by IHI, it seems likely that there were even more missing data beyond that described above (that is, hospitals that sporadically missed reporting months); we can only assume that a similar extrapolation strategy was used to patch these gaps as well. An 18-month cohort study of 3,000 hospitals would be expected to have 54,000 data points (3,000 hospitals × 18 months). For the campaign, the maximum possible number of data points is 38,700 (3,000 × 0.86 [hospitals with submissions] × 15 months]), a nearly 30% gap; the gap may well have been even greater (to our knowledge, this overall missing data figure has not been reported).

IHI advises that the confidence intervals on the mortality numbers are sufficiently large that individual hospitals should resist the impulse to scrutinize their own data to see whether they saved lives during the campaign period.[18] As an example, they describe a hypothetical average-size hospital with a typical raw mortality rate that fell by 10% during the campaign period. Although this hospital would appear to have saved 35 lives, "the 95 percent confidence interval for this statistic is quite large, approximately 16 to 85."[5(p. 3)] (Despite IHI's caution that individual hospitals should not report their own "lives saved" because of the high likelihood of random error, many did tout their successes, some with billboards, banners, or—in at least one case—colored seats in a football stadium marking lives saved in a local hospital). It is important to recognize that a large sample size (3,000 hospitals) helps reduce the impact of random error but does nothing to reduce systematic error, such as that generated by failure to adjust for secular trends in mortality (described later), or by inappropriate adjustments for case mix and for missing data. If there is systematic error, the large *N* might even provide false reassurance regarding the accuracy of the lives saved estimate.

How about the accuracy of the mortality data submissions themselves from the participating hospitals? IHI believes that these submissions were accurate ("we are confident in our results—even without hospital site audit…") and cites the lack of an incentive for individual hospitals to fake results (since only aggregate data are reported by IHI), the concreteness of the outcome (mortality), and the fact that hospitals are comparing their own results over different time frames ("the lives saved results will remain without bias as long as the results are applied consistently over time").[18] We are not as sure. First of all, the same social pressure that led 3,000 hospitals to sign up for the campaign might have squeezed the individuals responsible for reporting the mortality statistics at each institution. It does not take a graduate degree in epidemiology or human behavior to wonder whether the data submitted by a hospital's quality manager, under intense scrutiny from the CEO or board to demonstrate the hospital's success in quality improvement, is entirely accurate (particularly since many CEOs and managers are now operating under incentive systems that tie bonuses to quality performance). The sources of such inaccuracy could range from the tendency to double-check data that seem "wrong" (that is, no improvement) but accept without question data that seem "right," to subtle changes in clinical practice by providers or case managers to generate the hoped-for results (for example, a dying patient discharged to a hospice or skilled nursing facility would count as a "life saved" according to IHI's methodology).

Finally, IHI's decision to report the final results as a hard number (122,300) rather than a range or confidence interval conveys a false level of precision. (To be fair, IHI does report an estimate range [115,363–148,758] in some of its publications,[6,18] but these intervals were omitted from both its press release and most media reports). Contrast this with the IOM's now-famous estimate of deaths from medical errors in the United States (44,000–98,000), a range that makes clear the imprecision of the estimate.[3]

Can the Lives Saved Be Attributed to the Campaign?

Assuming that significant numbers of lives were saved by more widespread implementation of the six practices (an assumption we do not dispute), how much of the benefit can be attributed to the campaign activities themselves? The IHI's press release and public pronouncements do not emphasize the uncertainty around this question (nor did the media reports), but some of IHI's background materials appropriately did. As one article by IHI staffers states:

> The number of lives saved as calculated by IHI represents 'the number of lives saved by hospitals participating in the Campaign,' not 'the number of lives saved by the Campaign' or 'the number of lives saved from implementing the six Campaign interventions.'[5(p. 3)]

One important confounder is the fact that the campaign took place against a background of declining in-hospital mortality rates during the past several years.[5,6] Whether this decline is a result of some of the quality improvement efforts promoted by IHI and others, the growing implementation of other major organizational changes (such as the use of hospitalists, intensivists, stroke units, hospices, or electronic information systems), or the hospitalization of less ill patients (perhaps because of less aggressive managed care-driven barriers to hospitalization) is unknown. But the bottom line is that these secular trends could account for many of the "lives saved," a possibility that IHI acknowledges (and could have adjusted for, an adjustment that would have markedly lowered the "lives saved" estimate). "Indeed," write the IHI authors:

> to the patient who survives his or her hospital stay, it does not matter whether the improvement that saved his or her life was made because of the Campaign or because of another quality initiative (or the independent work of dedicated staff, or a combination of reasons.)[5(p.3)]

Although the above statement is undoubtedly true from the individual patient's standpoint, it is dangerously false from a systems perspective. The take-home message drawn by the media (and many of the participating hospitals) was that the lives saved were attributable to the campaign itself, thereby validating both the overall effort and the six sets of practices. In the absence of any rigorous evidence of the value of rapid response teams, for example, the campaign's results are already being taken as proof of concept, perhaps giving it the clinical and even the legal imprimatur of a standard of care.[19,20] It is important to recognize that resources, energy, and political capital being spent on such teams could also be spent on placing pharmacists on the wards, employing intensivists, building functioning electronic medical records, or improving nurse staffing ratios, all interventions whose evidence of benefit is presently more compelling.[11,21]

Overall, we end our analysis of the science unable to fully understand what actually happened at the organizational and patient levels as a result of the campaign or the independent impact of the campaign over preexisting efforts (it is possible that many "participating" organizations did little more than sign a pledge) and concerned about what appears, to us, to be substantial bias in the methodology behind the reported "lives saved" numbers. Evaluating quality improvement efforts, especially on a large scale, is difficult and requires the expertise of health services researchers, epidemiologists, and biostatisticians, as well as sophisticated database and data management abilities. Given the available resources, it was likely beyond the reach of the campaign to rigorously evaluate the results of the effort—but this is an argument for ensuring that large-scale campaigns possess the expertise and the resources to perform a proper evaluation, particularly when the implications of their results are so far reaching.

Policy Implications

The 100,000 Lives Campaign generated a huge amount of engagement by providers, organizations, and the media, and is worthy of consideration from a policy perspective. The idea of having national goals to improve health care (as in, for example, "The War on Cancer") or safety and quality (several professional societies have had campaigns around hand washing, for example) is not new and did not originate with the campaign. Nevertheless, in a crowded marketplace of accreditation standards, regulations, reporting, and cajoling, IHI succeeded in establishing and promoting a set of achievable goals for American hospitals. Perhaps this was the most noteworthy achievement of the campaign: the generation of unprecedented amounts of social pressure to participate.[22]

It was IHI's commanding presence that made this remarkable political and organizational tour de force possible. But the desire to play and to please—a perfectly natural sentiment since everyone wants improved quality and safety—is accompanied by some baggage. First, as we noted earlier, it creates methodologic problems that could introduce major scientific bias, such as in data reporting. Second, it could also lead to unquestioning acceptance of either methods or results that merit close scrutiny. As one small example, the two of us—both established and

well-funded investigators possessing what passes for tenure these days at our respective institutions—were asked by several colleagues whether "we were sure we wanted to do this" before writing this review. Less well-established researchers, providers, administrators, or individuals involved in quality and safety work might be even more reluctant to raise questions about the campaign or its results. This should be cause for concern because such an atmosphere could undermine both individual scientific inquiry and advances in quality improvement.

The campaign raises two important policy questions: Who should be driving efforts to improve quality and safety and how should target practices be selected? One can have nothing but admiration for IHI's courage in initiating the campaign (and for all of its many other contributions to improving health care). But should a private organization be setting a national agenda for change? Should this not be the role of organizations with better-defined roles in the health care system, organizations that are more fundamentally accountable to key stakeholders (including patients) and that have fewer opportunities for conflicts of interest? The latter point is important. The campaign allowed IHI to receive credit for many things that would have happened anyway (given the aforementioned "alignment"), created a landslide of "brand recognition" for the organization, and undoubtedly led to substantial new revenues and philanthropic dollars. We have absolutely no reason to believe that the dollars are being or will be used for anything but the highest purposes, but the conflict (or, at very least, appearance of conflict) is unavoidable.[23] A federal agency or regulator would not be vulnerable to such concerns.

And yet, no other broad based or governmental organization has succeeded in generating the same degree of passion for participation. As we dissect the 100,000 Lives Campaign for lessons, it will be important to discover the mix of ingredients (for example, people, tactics, message) that led to its successes in capturing the imagination of providers and hospitals. Clearly, there is much that other organizations can learn from IHI's efforts.

Conclusions

We applaud IHI for undertaking the 100,000 Lives Campaign, and the thousands of dedicated leaders, staff members, and providers around the United States for supporting its principles and working doggedly to improve health care quality and patient safety. Although the campaign highlighted the importance of social pressure in generating change, it also demonstrated the need for national organizations to develop rigorous processes to prioritize quality and safety interventions, use effective implementation methods, and apply robust evaluation strategies to determine whether and how patient care improved, and at what cost.

We also recognize the fundamental tensions inherent in this work. Campaigns are about "energizing the base," and they inevitably involve the selective use of statistics and evidence to promote a point of view and to catalyze action. In this way, IHI has been extraordinarily effective in moving the system to improve quality and safety. An IHI catechism is to ask "what can you fix by Tuesday?" and the campaign's successes are owed, in part, to this "just do it" philosophy. Too much statistical or epidemiological introspection could well have slowed down the effort. Yet more deliberate evaluation might have allowed it to answer a key question with greater clarity: What precisely was accomplished?

Our goal in writing this article is to catalyze discussions about the campaign (and, by extension, about efforts to improve safety and quality more generally) that are vigorous, respectful of divergent viewpoints, and, to the degree possible, evidence-based. In the end, we all have the same aim—to ensure that patients receive the safest, highest-quality care in American hospitals and clinics. Reaching this goal will require marrying inspiration with science; neither is independently sufficient.[24,25] It will be important to try to take full advantage of both sources of action, while resisting the trap of mistaking one for the other. J

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